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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,856	12/04/2003	Manne Satyanarayana Reddy	BULK 3.0-034	8301

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EXAMINER

LOEWE, SUN JAE Y

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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03/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

1. Claims 2-16 and 18-88 are pending in the instant application.

Response to Arguments

2. Applicant's arguments filed on December 19, 2007 have been fully considered but they are not persuasive. The following grounds of rejection are maintained:

- a) 35 USC 112 1st Paragraph Written Description (see response to arguments below, Section 4)
- b) 35 USC 112 1st Paragraph Enablement (see response to arguments below, Section 5)
- c) 35 USC 112 2nd Paragraph (see response to arguments below, Sections 6-7)
- d) 35 USC 102 (see response to arguments below, Section 8).

3. Applicant's arguments are successful in overcoming the 35 USC 112 2nd Paragraph rejection of the claims based on indefiniteness of the term "therapeutically effective amount." It is noted that the instant disclosure specifically defines "therapeutically effective amount." This ground of rejection is withdrawn.

Claim Rejections - 35 USC § 112 – 1st Paragraph

4. Written Description

Applicant argues:

.. It appears the Examiner suggests that the written description requirement necessitates inclusion of the entire X-ray pattern in the claims.

.....

It is well established in the law that the applicant is allowed to be own lexicographer. The Applicants have chosen to define the invention as a crystalline form of the compound having at least certain number of recited peaks. The Examiner is respectfully requested to set forth any law that prevents a patent applicant from doing so. ”

An x-ray diffraction pattern is a fingerprint that uniquely identifies a specific crystalline form. The presence and absence of peaks are important factors in establishing this fingerprint.

Applicant discloses crystalline forms identified by the XRD-pattern shown in Figure 1 or Figure 2 (ie. see claims 2 and 18). However, the claims require merely a few of the peaks shown in the XRD-pattern. Furthermore, the specification does not provide guidance or reasoning as to why an "abbreviated pattern" is sufficient to uniquely identify the claimed crystalline form.

Therefore, the claims are drawn to subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. Enablement

Applicant argues:

„An artisan is clearly instructed to take the explicitly described polymorphic form and put it together with clearly described excipients in the described manner. Thus, the issue of undue experimentation should not even arise. ”

A *prima facie* case of made based on the preparation of a pharmaceutical composition comprising the specifically claimed crystalline form. See office action dated June 25, 2007.

Claim Rejections - 35 USC § 112 2nd Paragraph

6. Applicant argues:

„ Claims 2 and 18 have been rejected as allegedly indefinite for incorporating a figure by reference. According to the Examiner, Applicants should recite the peaks of the XRD pattern instead. ”

Applicant is respectfully directed to page 4 of the office action dated June 25, 2007. See excerpts below:

" This rejection can be overcome by inserting the figure into the claims. ”

7. Applicant argues:

„ The proper test is “whether or not one skilled in the art could determine specific values . . . based on the disclosure.”

It is maintained that specific values cannot be determined for “prophylactically effective amount.” The instant specification does not provide a definition for the term 'prophylactically effective amount."

Claim Rejections - 35 USC § 102

8. Applicant argues:

„ The Examiner appears to suggest that the Examples of *Cosmesment* inherently anticipate the claimed polymorphic forms. ”

Applicant is respectfully directed to pages 11-12 of the office action dated June 25, 2007. See excerpts below:

“ As these forms differ from the claims in that the references are silent on the crystalline form, applicant must show that their crystalline form really is different from any of the ones prepared in the prior art. ”

.....

“ This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. Here the reference explicitly teaches exactly what the compound is. The only difference is a characteristic about which the reference happens to be silent. See also *Ex parte Anderson*, 21 USPQ 2nd 1241 and 1251, discussion of Rejection E. There, the decision states, “There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture.” (page 1253). ”

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe, Ph.D./
3-21-2008

/Kamal Saeed, Ph.D./
Primary Examiner
Art Unit 1626